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K001059
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DIALYSIS SOLUTIONS INC.
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510(k) SUMMARY

NORMOCARB
Sterile Bicarbonate
Renal Dialysis Concentrate

dsi *DIALYSIS SOLUTIONS INC.*
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March 31, 2000

510(k) Summary

NORMOCARB
Sterile Bicarbonate Renal Dialysis Concentrate

NAME OF DEVICE

Trade or Proprietary Name: NORMOCARB
(Sterile Bicarbonate Renal Dialysis Concentrate)

Classification Name: Hemodialysis Systems and Accessories
(dialysate concentrate for hemodialysis),
as per 21 CFR 876.5820.

DESCRIPTION AND INTENDED USE

NORMOCARB is a clear, sterile, apyrogenic, calcium-free bicarbonate renal dialysis concentrate provided in 240 mL unit-dose vials which, when diluted with water in the required proportions, creates a dialysis solution or dialysate for use in hemodialysis.

Once prepared, the dialysate is indicated for use in Continuous Renal Replacement Therapy (CRRT), which is a dialysis continued 24 hours a day to treat critically ill patients with renal failure. CRRT is usually administered to patients in intensive care who require dialysis and are hemodynamically unstable, or whose liver function is either impaired or at risk of impairment. Patients with liver impairment typically are more challenging to manage and may have high requirements for bicarbonate due to ongoing lactic acidosis. The use of lactate-based solutions for dialysis may not correct metabolic acidosis if the liver cannot metabolize more lactate into bicarbonate. The bicarbonate-free, lactate-containing dialysis solution will actually remove some bicarbonate from the patient. In addition to a bicarbonate-based dialysis solution, patients with liver impairment and/or severe metabolic acidosis may require additional intravenous infusions of bicarbonate to maintain their pH within acceptable parameters.

The aims of CRRT are control of fluid balance, control of plasma electrolytes, control of acid-base balance and removal of products of metabolism.

SUBSTANTIAL EQUIVALENCE

The following table summarizes the similarities and differences between Renasol® Bicarbonate Hemodialysis Concentrate and NORMOCARB Sterile Bicarbonate Renal Dialysis Concentrate; a discussion of these comparisons follows:

SUBSTANTIAL EQUIVALENCE (Cont'd)

Comparison of Renasol® vs. NORMOCARB		
Product Characteristic	**Renasol® K792213 and K781967**	**NORMOCARB**
Intended Use:	Dialysate concentrate for use in hemodialysis.	Dialysate concentrate for use in hemodialysis.
Components and Composition (Diluted):	All raw materials are tested to USP standards.	All raw materials are tested to, and meet, USP standards.
	Product Code SB-1030: Sodium: 139 mEq/L Magnesium: 1.00 mEq/L Chloride: 101.00 mEq/L Acetate: 4.00 mEq/L Dextrose: 200 mg/dL Bicarbonate: 35.00 mEq/L	Sodium: 140.0 mEq/L Magnesium: 1.5 mEq/L Chloride: 106.5 mEq/L Bicarbonate: 35.0 mEq/L Dextrose (if added)*: 10.2 mEq/L
Sterility:	Renasol is not manufactured as a sterile product.	NORMOCARB is manufactured as a sterile, pyrogen-free product.
Container/Closure:	The acetate concentrate is packaged in 3.78 L (4 gallon) plastic containers. The sodium bicarbonate concentrate is available in packets (dry) and in plastic bags or containers (liquid).	The complete bicarbonate concentrate is packaged in clear, glass serum vials, closed with an elastomeric serum stopper and sealed with an aluminum crimp cap with a polypropylene cover.
Diluent:	Purified Water meeting AAMI Standards.	Sterile water - exceeds AAMI standards.

* If required in patients on insulin or with hypoglycemia, 12 mL of D50W may be added upon dilution, resulting in a concentration of dextrose in the dialysate of 10.2 mEq/L.

Intended Use:

Both Renasol® and NORMOCARB are bicarbonate-based dialysate concentrates for hemodialysis, as per 21 CFR 876.5820 Hemodialysis Systems and Accessories. Both products, when diluted, create a dialysate solution for use in renal dialysis therapy for the removal or delivery of compounds or electrolytes that the failing kidney cannot excrete or retain in the proper concentrations.

Renasol® is used for chronic renal hemodialysis, which is an intermittent treatment regimen used in the chronic care dialysis unit. NORMOCARB is intended for use in Continuous Renal Replacement Therapy (CRRT), which is a dialysis continued 24 hours a day to treat critically ill patients in the intensive care unit. The differences between NORMOCARB and Renasol® highlighted in this section demonstrate the suitability of NORMOCARB for the intensive care setting.

SUBSTANTIAL EQUIVALENCE (Cont'd)

Components and Composition:
The raw materials of both Renasol® and NORMOCARB are tested to USP standards.

The diluted compositions of Renasol® (SB-1030 formulation) and NORMOCARB are very similar, as is demonstrated in the table above. The two products contain the same components, in comparable concentrations, with the exception of acetate (4.0 mEq/L) and dextrose (200 mg%) in the Renasol® formulation.

Dextrose is often present in dialysis solutions used for chronic therapy where there is a risk that diabetic patients, in the presence of insulin, may develop low blood sugar levels resulting in hypoglycemia. However, hypoglycemia is not a risk with dialysates to be used in Continuous Renal Replacement Therapy (CRRT), due to the slower rate of administration. In addition, certain patients are unable to handle the dextrose delivered by dialysates usually employed for CRRT. Therefore, NORMOCARB has not been formulated to contain dextrose. However, in situations where dextrose may be required, such as for pediatric patients where hypoglycemia may be a concern or for patients on insulin, 12 mL of D50W may be added to the sterile water as part of the dialysate at the discretion of the physician, resulting in a concentration of 10.2 mEq/L of dextrose in the dialysate.

Acetate is used in Renasol® to lower the pH of the solution to prevent carmelization due to the presence of dextrose and/or minimize precipitation when the bicarbonate concentrate is added in the dialysis machine. Since these are not considerations with NORMOCARB, acetate is not included in this formulation.

Renasol® is made available as two separate concentrates: the SB-1000 liquid acid concentrates series and the BC-1 Series Sodium Bicarbonate Concentrate. Renasol® Bicarbonate Hemodialysis Concentrate is obtained by mixing the two concentrates in a compatible 36.83 dilution three stream artificial kidney (hemodialysis) machine. For every 36.83 volume parts of dialysate, 1 volume part of acid concentrate (SB-1000 series) is mixed with 1.83 volume parts of the BC-1 Series Sodium Bicarbonate Concentrate with 34 volume parts of Purified Water (AAMI quality or equivalent).

NORMOCARB is available as a complete concentrate containing all components, including the bicarbonate. The dialysate is prepared in a single-step process of dilution using 240 mL of NORMOCARB concentrate with 3 liters of sterile water to make 3.24 liters of dialysate.

Sterility:
Renasol® is not a sterile product. NORMOCARB is sterile and pyrogen-free. While no bacteria can cross the dialysis membrane into blood, pyrogens can. Relatively stable patients in the chronic dialysis unit do not respond severely adversely to small amounts of pyrogens, although there is more and more literature calling for very pure, and even sterile, solutions. A critically ill patient in the ICU setting, however, can be adversely affected by any pyrogen and it is necessary to avoid the risk of pyrogens altogether in this setting. If a solution is not completely sterile there is a risk of release of pyrogens. Therefore, there

SUBSTANTIAL EQUIVALENCE (Cont'd)

Sterility (Cont'd):
is certain benefit to using a sterile dialysate, in particular for critically ill patients receiving dialysis treatment.

Container/Closure:
The Renasol® acid concentrate is packaged in 4 L plastic bottles or 55 gallon drums. The sodium bicarbonate concentrate is available in packets (dry) and in plastic bags or containers (liquid). NORMOCARB is packaged in depyrogenated 250 mL clear glass serum vials, which are sealed with steam-sterilized grey, elastomeric serum stoppers and aluminum crimp caps with royal blue polypropylene covers.

A number of factors led to the use of 250 mL glass vials for the containment of NORMOCARB. First and foremost, glass is well known for its inert and non-reactive qualities. Therefore, any reaction between the NORMOCARB concentrate and the glass vial, which could lead to the formation of undesired material in the product, is unlikely. This type of reactivity is more likely to occur with the use of plastic containers and, in addition, materials from the plastic itself can leach into the product. Glass is also much more effective than plastic as a barrier to adhesives and inks from labeling attached to, or printed on, the container.

Lastly, NORMOCARB is available in a single-use quantity of 240 mL and is, therefore, less susceptible to product contamination than concentrates available in bulk, multi-use quantities.

Diluent:
The Renasol® labeling instructs the user to dilute the concentrate using Purified Water (AAMI standard or equivalent). The NORMOCARB labeling instructs the user to dilute the concentrate using sterile water, a higher quality water than purified water or AAMI standard equivalent, in order to maintain the sterile quality of the NORMOCARB concentrate.

CONCLUSIONS

NORMOCARB and Renasol® are both bicarbonate renal dialysis concentrates with the same intended use and are very similar in composition (diluted). These similarities demonstrate the substantial equivalence of NORMOCARB and Renasol®.

However, there are several noteworthy features that distinguish NORMOCARB from Renasol®. NORMOCARB is manufactured as a sterile, pyrogen-free concentrate packaged in 250 mL single-use glass vials. The sterile quality of the product, the nature of the packaging materials, and the single-use fill volume (240 mL) provide for low risk of product contamination. In addition, NORMOCARB is available as a complete concentrate, including the bicarbonate, which requires only a single step of dilution with sterile water for preparation of the dialysate. These safety and convenience factors make NORMOCARB ideally suited for its intended use for CRRT in the intensive care setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2000

Dialysis Solutions, Inc.
c/o Joseph W. Beyger
Vice President, Regulatory Affairs
Novex Pharma
380 Elgin Mills Road East
Richmond Hill, Ontario
CANADA L4C 5H2

Re: K001059
NORMOCARB (Sterile Bicarbonate Renal Dialysis Concentrate)
Dated: March 31, 2000
Received: April 3, 2000
Regulatory class: II
21 CFR §876.5820/Procode: 78 KPO

Dear Mr. Beyger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

IV) STATEMENT OF INDICATIONS FOR USE

NORMOCARB Sterile Bicarbonate Renal Dialysis Concentrate, after dilution, is indicated for use in Continuous Renal Replacement Therapy (CRRT).

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001059

Prescription use ✓